K102644

NOV 23 2011

Traditional 510(k) Summary of Safety and Effectiveness for the

ADVIA® 2120/2120i Hematology auto-analyzers

This summary of Traditional 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Date of Preparation: February 23, 2011

B. Proprietary and Established Names:

ADVIA® Hematology Auto analyzers

C. Applicant:

Siemens Healthcare Diagnostics Inc., 511 Benedict Ave, Tarrytown, NY 10591

Ernest Joseph, Senior Manager, Regulatory Affairs

Office: (914) 524-2431 Fax: (914) 524-2101

D. Regulatory Information:

Proprietary Name: ADVIA® Hematology Auto analyzers

Common name: Automated Hematology analyzer

1. Classification number: 21 CFR § 864.5200, 864.5220 Automated Differential Cell Counter

2. Classification: Class II

3. Product Code: GKZ

4. Panel: Hematology

E. Predicate Device:

ADVIA 2120 and 2120i Hematology Auto analyzers with current CPU board which was cleared on 9/17/2004(K042251)

F. Device Description:

The ADVIA 2120/210i Hematology systems with Auto slide are an integrated option of a Hematology analyzers with complete blood cell count, leukocyte differential cell count, reticulocyte analysis capability, nucleated red blood cell count, quantitative determination of blood cells in Cerebrospinal Fluid (CSF), enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens and a slide stainer designed to provide reflexive slide making/staining without user intervention based upon pre-selected, user-definable criteria.

The ADVIA 2120/210i Hematology systems with Auto slide consists of the following: an analytical module that aspirates, dilutes, and analyzes whole blood samples; an auto sampler that automatically mixes, identifies, and presents the samples for processing; a computer workstation that controls the instrument, provides primary user interface with the instrument and manages the data produced by the instrument; a printer that optionally generates reports based on the instrument results and an auto slide module that prepares a wedge smear from a drop of blood, places it on a microscope slide and stains the slide in accordance with Wright, Wright-Giemsa and May-Grnwald Giemsa Staining techniques.

The ADVIA 2120/210i with Auto slide reports the following hematological parameters:

White Blood Cell Parameters
WBC- white blood cell count
Neut- neutrophil count (percentage and absolute counts)
Lymph- lymphocyte count (percentage and absolute counts)
Mono- monocyte count (percentage and absolute counts)
Eos- eosinophil count (percentage and absolute counts)
Baso- basophil count (percentage and absolute counts)
LUC- large unstained cell count (percentage and absolute counts)
NRBC- Nucleated Red cell count (percentage and absolute counts)

Red Blood Cell Parameters
RBC- red blood cell count
Hct- hematocrit
MCV- mean corpuscular volume
RDW- red cell volume distribution width
CHCM- hemoglobin concentration mean
HDW- hemoglobin concentration distribution width

Hemoglobin Parameters
Hgb- hemoglobin concentration
MCH- mean corpuscular hemoglobin

MCHC- mean corpuscular hemoglobin concentration
CH- cellaur hemoglobin

Platelet Parameters
Plt- platelet count
MPV- mean platelet volume

Reticulocyte Count
Retic- reticulocyte count (percentage and absolute counts)
MCVg- mean corpuscular volume of all gated red cells
MCVr- mean corpuscular volume of reticulocytes
CHCMg- hemoglobin concentration mean of all gated red cells
CHCMr- hemoglobin concentration mean of reticulocytes
CHg- mean hemoglobin content of all gated red cells
CHr- mean hemoglobin content of reticulocytes

In addition the ADVIA 2120 with Autoslide reports the following parameters with Cerebrospinal Fluid samples using the CSF method cleared for use on the ADVIA 120 under K022331:

White Blood Cell Parameters
WBC- white blood cell count
Neut- neutrophil count (percentage and absolute counts)
Lymph- lymphocyte count (percentage and absolute counts)
Mono- monocyte count (percentage and absolute counts)
MN- mononuclear count (percentage and absolute counts)
PMN- polymorphonuclear count (percentage and absolute counts)

Red Blood Cell Parameters
RBC- red blood cell count

Body Fluids (pleural, peritoneal, and peritoneal dialysis) Parameters:
RBC – red blood cell count
TNC – Total nucleated cell count (including WBC count)

G. Intended Use:

The ADVIA 2120 and ADVIA 2120i with autoslide are quantitative, automated hematology analyzers that provide the following information for in vitro diagnostic use in clinical laboratories:

- A complete blood count (CBC) consisting of WBC, RBC, Hgb, CN-Free Hgb, Calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, CH, Plt, MPV.

- A leukocyte differential count consisting of Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#) Baso (%/#), LUC (%/#).
- A reticulocyte analysis consisting of Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr.
- A nucleated red blood cell count consisting of NRBC(%/#).
- Enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens.

Note: Above measurands are determined (in whole blood, pleural, peritoneal, or peritoneal dialysis specimens with K2 and/or K3 EDTA anti-coagulants).

- Quantitative determination of blood cells in Cerebrospinal Fluid (CSF) consisting of WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#),PMN (%/#).

In addition, the system provides the added capability to automatically prepare and stain high quality blood smears on a microscope slide.

H. Substantial Equivalence Information:

This traditional 510(k) is submitted for a replacement of the Analytical Module (AM) CPU board in the ADVIA 2120/2120i Hematology Autoanalyzers –

Prior 510k Clearances:

K930148 (H*3)(Reticulocyte) measurands/parameters cleared on, (Retic, MCVg, MCVr, CHCMg, CHCMr, CHg, CHr.

K954954 (Reticulocyte) measurands/parameters cleared, (Retic, MCVg, MCVr, CHCMg, CHCMr, CHg, CHr.

K971998 (ADVIA 120) (cleared all parameters under device description except body fluids and CSF).

K003796 (ADVIA 120)(CSF) measurands/parameters cleared (CSF WBC, Neuts, Lymphs Mono's MN's,PMN's)

K012904 (ADVIA 120) measurands/parameters cleared (CN-free Hgb)

K022668 (ADVIA 120) measurands/parameters cleared (Calculated Hgb)

K022331 (ADVIA 120) revised measurands/parameters cleared (CSF WBC, Neuts, Lymphs Mono's MN's,PMN's)

K042251 (ADVIA 2120), (cleared all parameters under device description except body fluids)

K051693 (ADVIA 2120 with Auto slide and NRBC), (cleared all parameters under device description except body fluids)

K090346 - ADVIA 2120/2120i Body fluids Application) measurands/parameters cleared RBC, TNC).

Please note that ADVIA 2120i with auto slide was cleared in accordance with replacement Reagent and Instrument family policy guidance provided by FDA.

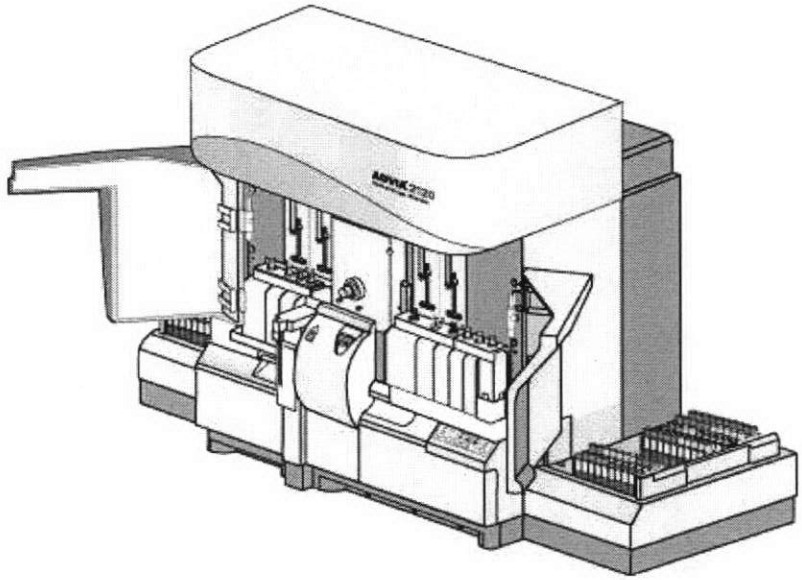
The AM CPU board utilized in the ADVIA 2120 / 2120i Hematology devices is nearing technology obsolescence. In order to address this obsolescence issue, the following device technology obsolescence changes were performed:

- Implement new device component (CPU board for the analytical subsystem)

- Upgrade the Nucleus Operating System version to a newer version that supports the new CPU board.

- Modify / compile the device application software to function with the new CPU board.

A comparison of the important similarities and differences between ADVIA 2120/2120i analyzers with the ARM9 CPU board and current CPU board (predicate) are shown in the following tables:

Similarities:			
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**		**ADVIA 2120/2120i with ARM9 CPU**
Overview	The ADVIA 2120i hematology system is a fully automated diagnostic instrument. The analyzer uses whole blood samples to provide complete blood counts (CBC), white cell differential counts (Diff), and reticulocyte absolute, percent and indices counts (Retic). 		Same
Parameters	CBC Results	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, CHCM, RDW, HDW, CH, PLT	Same

Similarities:				
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**			**ADVIA 2120/2120i with ARM9 CPU**
	Differential Results	NEUT, LYMPH, MONO, EOS, BASO, LUC, NRBC (% and absolute)		
	Platelet Results	PLT, MPV		
	Reticulocyte Results	%RETIC, #RETIC, MCVr, CHCMr, CHr, MCVg, MCVr, CHCMg, CHg		
	CSF Results	CSF RBC, CSF WBC, CSF MN, CSF PMN, CSF NEUT, CSF LYMPH, CSF MONO		
	BF Results	TNC, RBC		
Morphology Results	WBC:	Left Shift, Atypical Lymph, Blasts, Immature Granulocytes, Myeloperoxidase Deficiency		Same
	RBC and PLT:	NRBC, ANISO, MICRO, MACRO, HC VAR, HYPO, HYPER, RBC Fragments, RBC Ghosts, Platelet Clumps, Large Platelets		
Performance				
Linearity	**Parameter**	**Range**	**Maximum Deviation (whichever is greater)**	Same
	WBC (10^3/µL)	0.02 to 400	0.5 or 5.0%	
	RBC (10^6/µL)	0.0 to 7.0	0.1	
	HGB (g/dL)	0 to 22.5	0.2 or 2.0%	
	PLT (10^3/µL)	5.0 to 3500	5.0 or 5.0%	
	%RETIC	0.2 to 24.5	5.0%	

Similarities:					
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**				**ADVIA 2120/2120i with ARM9 CPU**
	CN-free HGB (g/dL)	1 to 22.5	0.3 or 3.0%		
	CSF WBC (cells/ µL)	0 to 50	5		
		50 to 5000	10%		
	CSF RBC (cells/ µL)	0 to 50	5		
		50 to 1500	10%		
	BF TNC (10^3/µL)	0.02 to 400	10 cells or ≤10.0%		
	BF RBC (10^6/µL)	0.01 to 6.76	10 x 10^3 cells or ≤10.0%		
Within-Run Precision	**Parameter**	**Nominal Level**	**Standard Deviation**	**Coefficient Variation%**	Same
	WBC (10^3/µL)	7.5	0.2	2.66	
	RBC (10^6/µL)	5.0	0.06	1.2	
	HGB (g/dL)	15.0	0.14	0.93	
	MCV (fL)	90.0	0.7	0.78	
	CHCM (g/dL)	32.0	0.25	0.8	
	RDW (%)	13.0	0.25	1.92	
	HDW (g/dL)	2.8	0.1	3.57	
	PLT (10^3/µL)	300	8.8	2.93	
	MPV (fL)	8	0.2	2.5	
	%NEUT	65	1.4	2.15	
	%LYMPH	25	1.1	4.4	
	%MONO	6	0.9	15	
	%EOS	2	0.5	25	
	%BASO	1	0.5	50	
	%LUC	2	0.5	25	
	%RETIC	2	0.25	12.5	
	CN-free HGB (g/dL)	15.0	0.20	1.33	
	CSF WBC	100	15	15.0	
	CSF RBC	100	15	15.0	
	#CSF MN	100	20	20%	

Similarities:					
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**				**ADVIA 2120/2120i with ARM9 CPU**
	#CSF PMN %NRBC BF TNC (cells/µL) BF RBC (10^3 cells/µL)	100 n/a 500 50	20 <6 n/a n/a	20% <30 <15 <10	
Carryover	Less than or equal to 1%				Same
Computers & Operating Systems					
Real-time Control					
	multiple distributed real-time microcontrollers				Same
User Interface personal computer	• Intel based processor • Windows 2000 • Floppy drive • Network card • Modem				Same
User Interface external peripherals	• Keyboard • Mouse • Hand-held barcode scanner • Printer				Same
Physical Specifications					
Electrical Power	Voltage selectable for single-phase: 100 Vac (6 Amps) - 240 Vac (3 Amps) Frequency: 50/60Hz				Same
Temperature	Operating: 18℃ to 32℃ Storage:-29℃ to 60℃				Same
Relative Humidity	Operating: 15%-80% (noncondensing)				Same
Audible Noise Level	65 decibels				Same
Weight (with	193 kg				Same

Similarities:		
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**	**ADVIA 2120/2120i with ARM9 CPU**
Autosampler and reagents)		
Height	86cm	Same
Width	141 cm	Same
Depth	68 cm	Same
Vacuum/Pressure	• 40 psi line: 38 to 42 psi • 20 psi line: 19 to 21 psi • 5 psi line: 4.5 to 5.5 psi • 20" Hg line: 19 to 21" HG	Same
Reaction Chamber Temperature	• Perox chamber: 58 to 72 ℃ • Baso chamber: 32 to 34 ℃	Same
Power Pack Temperature	• Ambient: 18 to 35 ℃ • Fuse side: 18 to 40 ℃ • Filter side: 18 to 40 ℃	Same
Light Intensities	• Tungsten Lamp: 90 to 125 • Laser: 150 to 205	Same
Power Supply Voltages	• +5 volts Switched: 4.92 to 5.27 V • +5 volts Unswitched: 4.87 to 5.33 V • +12 volts Switched: 11.2 to 13.01 V • -12 volts: -11.2 to -13.01 V • +15 volts Switched: 14.56 to 15.63 V • -15 volts: -14.56 to -15.63 V • +24 volts: 22.46 to 25.58 V • Perox Lamp +5 volts: 4.82 to 5.176 V	Same
Sample Mode Volumes	Automatic Closed-Tube: 175µL Manual Closed-Tube: 175µL Manual Open-Tube: 175µL	Same
Test Selectivity/	CBC 120 Samples/hr	Same

Similarities:		
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**	**ADVIA 2120/2120i with ARM9 CPU**
Throughput	CBC/Diff 120 Samples/hr CBC/Diff/Retic 74 Samples/hr CBC/Retic 74 Samples/hr Retic 74 Samples/hr With Autoslide slide making enabled: CBC 108 Samples/hr CBC/Diff 108 Samples/hr	
Autosampler		
Sample Capacity	150 samples 15 racks of 10 tubes	Same
Tube Sizes	10-13 mm diameter 50-100 mm height	Same
Tube Types	Some of the allowable tube types: Standard VACUTAINER ® HEMOGARD ® Center puncture Monovette ® Venoject ® II	Same
Barcode reader	Reads up to 14 digits Automatic label code discrimination Compatible barcode types: 1. Codabar 2. Interleaved 2 of 5 3. Code 39 4. Code 128 5. EAN and JAN (8 and 13)	Same

Similarities:		
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**	**ADVIA 2120/2120i with ARM9 CPU**

Data Management	• TDC version 9 or higher
	• Database storage capacity of 10,000 records, including graphics
	• Review and edit capability
	  o User-defined windows
	  o User-defined reports
	  o User-defined ranges based on age and sex for Normal, Rerun, Panic, and Delta Check criteria
	• Bi-directional and host query communication protocols
	• Quality control
	  o 3D bar graph
	  o Levey-Jennings plot
	  o SDI graph
	  o Table format
	• Remote QC
	• ILQC programs
	• Patient moving average
	• User assistance
	  o Context sensitive help
	  o Operator's guide
	  o Procedure wizards
	  o Problem solving diagnostics
	  o Remote diagnostics
		Same

Consumables		

Reagents	• CBC TIMEPAC
	  o Baso
	  o HGB
	  o RBC/PLT
	  o Defoamer
	• CN-Free CBC TIMEPAC
		Same

Similarities:		
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**	**ADVIA 2120/2120i with ARM9 CPU**
	○ Baso ○ CN-Free HGB ○ RBC/PLT ○ Defoamer • DIFF TIMEPAC ○ Perox 1 ○ Perox 2 ○ Perox 3 ○ Perox Sheath • autoRetic • EZ KLEEN • Sheath/Rinse • CSF	
Calibrators	• ADVIA OPTIpoint • ADVIA SETpoint	Same
Controls	• ADVIA TESTpoint Low • ADVIA TESTpoint Normal • ADVIA TESTpoint High • ADVIA TESTpoint Retic Low • ADVIA TESTpoint Retic High • ADVIA TESTpoint 3-in-1 Abnormal1 • ADVIA TESTpoint 3-in-1 Normal • ADVIA TESTpoint 3-in-1 Abnormal2	Same

Differences:		
Specification	**ADVIA 2120 and 2120i with current CPU (predicate)**	**ADVIA 2120/2120i with ARM9 CPU**
Computers & Operating Systems		
Real-time Control	Intel 386ex CPU running Nucleus OS	ARM9 CPU running Nucleus OS
User Interface software	ADVIA 2120/2120i user interface software (v5.8)	ADVIA 2120/2120i user interface software (v6.0)
Communication Interface	BNC Ethernet cable (10Base-2)	RJ-45 Ethernet Cable (100Base-TX)

I. Conclusion:

There are no new software features, functionality, or capabilities associated with ADVIA 2120/2120i analyzers. The operating system change coupled with the modification / re-compilation of the application software does not affect the intended use of the devices, nor does it alter the fundamental scientific technology of the devices, thus not affecting or changing safety and effectiveness of the device from previously cleared ADVIA 2120/2120i devices CSF, nRBC and Body Fluids methods. Therefore, ADVIA 2120/2120i auto analyzers with current CPU board are substantially equivalent with the new ARM9 CPU board.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics
c/o Mr. Gerry Sadrakula
Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, NY 10591

NOV 2 3 2011

Re: k102644
Trade/Device Name: ADVIA® 2120 Hematology Auto analyzer
ADVIA® 2120i Hematology Auto analyzer with Auto slide
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. Sadrakula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) K102644

Device Name: ADVIA® 2120/2120i Hematology auto-analyzers

Indications for Use:

The ADVIA 2120 and ADVIA 2120i with autoslide are quantitative, automated hematology analyzers that provide the following information for in vitro diagnostic use in clinical laboratories:

- A complete blood count (CBC) consisting of WBC, RBC, Hgb, CN-Free Hgb, Calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, CH, Plt, MPV.
- A leukocyte differential count consisting of Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#) Baso (%/#), LUC (%/#).
- A reticulocyte analysis consisting of Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr.
- A nucleated red blood cell count consisting of NRBC(%/#).
- Enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens.

Note: Above measurands are determined (in whole blood, pleural, peritoneal, or peritoneal dialysis specimens with K2 and/or K3 EDTA anti-coagulants).

- Quantitative determination of blood cells in Cerebrospinal Fluid (CSF) consisting of WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#),PMN (%/#).

In addition, the system provides the added capability to automatically prepare and stain high quality blood smears on a microscope slide.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102644